Amendments to the Specification:

Please replace the paragraph beginning at page 2, line 16, with the following redline paragraph:

There exists a need in the art for improved compositions and methods for improving or maintaining the integrity of body passageways or cavities. The present invention addresses the problem associated with the existing procedures, offers ~~signifimayt~~ significant advantages over existing procedures, and provides other related advantages.

Please replace the paragraph beginning at page 3, line 1, with the following redline paragraph:

In one aspect, the instant invention provides delivery devices that include a one or more therapeutic agents and a mesh, wherein the mesh includes a biodegradable polymer. The therapeutic agents may be utilized to treat or prevent a wide variety of conditions, including, for example, iatrogenic complications of arterial and venous catheterization, ePTFE graft placement, aortic dissection, cardiac rupture, aneurysm, cardiac valve dehiscence, passageway rupture and surgical wound repair. Another condition includes intimal hyperplasia, which may arise at various graft sites. For example, intimal hyperplasia may arise at an anastomotic site, such as at a venous anastomosis, an arterial anastomosis, an arteriovenous fistula, an arterial bypass, or an arteriovenous graft. Representative body passageways and cavities that may be treated include, for example, arteries, veins, the heart, the esophagus, the stomach, the duodenum, the small intestine, the large intestine, the biliary duct, the ureter, the bladder, the urethra, the lacrimal ducts, the trachea, bronchi, bronchiole, nasal passages (including the sinuses) and other airways, eustachian tubes, the external auditory ~~mayal~~ canal, the vas deferens and other passageways of the male reproductive tract, the uterus and fallopian tubes and the ventricular system (cerebrospinal fluid) of the brain and the spinal cord. Representative examples of cavities include, for example, the abdominal cavity, the buccal cavity, the peritoneal cavity, the pericardial cavity, the pelvic cavity, perivisceral cavity, pleural cavity, inguinal ~~mayal~~ canal and uterine cavity.

Please replace the paragraph beginning at page 9, line 6, with the following redline paragraph:

In another embodiment, the ~~bioddegradable~~ biodegradable polymer carrier may include hyaluronic acid, chitosan, or sodium alginate.

Please replace the paragraph beginning at page 11, line 13, with the following redline paragraph:

"Body passageway" as used herein refers to any of number of passageways, tubes, pipes, tracts, ~~mayals~~ canals, sinuses or conduits which have an inner lumen and allow the flow of materials within the body. Representative examples of body passageways include arteries and veins, lacrimal ducts, the trachea, bronchi, bronchiole, nasal passages (including the sinuses) and other airways, eustachian tubes, the external auditory ~~mayal~~ canal, oral cavities, the esophagus, the stomach, the duodenum, the small intestine, the large intestine, biliary tracts, the ureter, the bladder, the urethra, the fallopian tubes, uterus, vagina and other passageways of the female reproductive tract, the vas deferens and other passageways of the male reproductive tract, and the ventricular system (cerebrospinal fluid) of the brain and the spinal cord.

Please replace the paragraph beginning at page 11, line 23, with the following redline paragraph:

"Body cavity" as used herein refers to any of number of hollow spaces within the body. Representative examples of cavities include, for example, the abdominal cavity, the buccal cavity, the peritoneal cavity, the pericardial cavity, the pelvic cavity, perivisceral cavity, pleural cavity, inguinal ~~mayal~~ canal and uterine cavity.

Please replace the paragraph beginning at page 13, line 10, with the following redline paragraph:

The therapeutic agents, therapeutic devices or compositions and pharmaceutical devices or compositions provided herein may be placed within one or more containers, along with packaging material that provide instructions regarding the use of such materials. These

containers may or may not contain a ~~dessimayt~~ desiccant. Generally, such instructions include a tangible expression describing the reagent concentration, as well as within certain embodiments, relative amounts of excipient ingredients or diluents (*e.g.,* water, saline or PBS) that may be necessary to reconstitute the pharmaceutical composition. The containers and contents therein may also be sterile.

Please replace the paragraph beginning at page 17, line 3, with the following redline paragraph:

Other representative anthracyclines include, FCE 23762 doxorubicin derivative (Quaglia *et al., J. Liq. Chromatogr. 17*(18):3911-3923, 1994), annamycin (Zou *et al., J. Pharm. Sci. 82*(11):1151-1154, 1993), ruboxyl (Rapoport *et al., J. Controlled Release 58*(2):153-162, 1999), anthracycline disaccharide doxorubicin analogue (Pratesi *et al., Clin. Cancer ~~Mayeer~~ Res. 4*(11):2833-2839, 1998), N-(trifluoroacetyl)doxorubicin and 4'-O-acetyl-N-(trifluoroacetyl)doxorubicin (Berube & Lepage, *Synth. Commun. 28*(6):1109-1116, 1998), 2-pyrrolinodoxorubicin (Nagy *et al., Proc. Nat'l Acad. Sci. U.S.A. 95*(4):1794-1799, 1998), disaccharide doxorubicin analogues (Arcamone *et al., J. Nat'l ~~Mayeer~~ Cancer Inst. 89*(16):1217-1223, 1997), 4-demethoxy-7-O-[2,6-dideoxy-4-O-(2,3,6-trideoxy-3-amino-α-L-lyxo-hexopyranosyl)-α-L-lyxo-hexopyranosyl] adriamicinone doxorubicin disaccharide analog (Monteagudo *et al., Carbohydr. Res. 300*(1):11-16, 1997), 2-pyrrolinodoxorubicin (Nagy *et al., Proc. Nat'l Acad. Sci. U. S. A. 94*(2):652-656, 1997), morpholinyl doxorubicin analogues (Duran *et al., ~~Mayeer~~ Cancer Chemother. Pharmacol. 38*(3):210-216, 1996), enaminomalonyl-β-alanine doxorubicin derivatives (Seitz *et al., Tetrahedron Lett. 36*(9):1413-16, 1995), cephalosporin doxorubicin derivatives (Vrudhula *et al., J. Med. Chem. 38*(8):1380-5, 1995), hydroxyrubicin (Solary *et al., Int. J. ~~Mayeer~~ Cancer 58*(1):85-94, 1994), methoxymorpholino doxorubicin derivative (Kuhl *et al., ~~Mayeer~~ Cancer Chemother. Pharmacol. 33*(1):10-16, 1993), (6-maleimidocaproyl)hydrazone doxorubicin derivative (Willner *et al., Bioconjugate Chem. 4*(6):521-7, 1993), N-(5,5-diacetoxypent-1-yl) doxorubicin (Cherif & Farquhar, *J. Med. Chem. 35*(17):3208-14, 1992), FCE 23762 methoxymorpholinyl doxorubicin derivative (Ripamonti *et al., Br. J. ~~Mayeer~~ Cancer 65*(5):703-7, 1992), N-hydroxysuccinimide ester doxorubicin

derivatives (Demant *et al.*, *Biochim. Biophys. Acta 1118*(1):83-90, 1991), polydeoxynucleotide doxorubicin derivatives (Ruggiero *et al.*, *Biochim. Biophys. Acta 1129*(3):294-302, 1991), morpholinyl doxorubicin derivatives (EPA 434960), mitoxantrone doxorubicin analogue (Krapcho *et al.*, *J. Med. Chem. 34*(8):2373-80. 1991), AD198 doxorubicin analogue (Traganos *et al.*, ~~*Mayeer*~~ *Cancer Res. 51*(14):3682-9, 1991), 4-demethoxy-3'-N-trifluoroacetyldoxorubicin (Horton *et al.*, *Drug Des. Delivery 6*(2):123-9, 1990), 4'-epidoxorubicin (Drzewoski *et al.*, *Pol. J. Pharmacol. Pharm. 40*(2):159-65, 1988; Weenen *et al.*, *Eur. J.* ~~*Mayeer*~~ *Cancer Clin. Oncol. 20*(7):919-26, 1984), alkylating cyanomorpholino doxorubicin derivative (Scudder *et al.*, *J. Nat'l* ~~*Mayeer*~~ *Cancer Inst. 80*(16):1294-8, 1988), deoxydihydroiodooxorubicin (EPA 275966), adriblastin (Kalishevskaya *et al.*, *Vestn. Mosk. Univ., 16*(Biol. 1):21-7, 1988), 4'-deoxydoxorubicin (Schoelzel *et al.*, *Leuk. Res. 10*(12):1455-9, 1986), 4-demethyoxy-4'-o-methyldoxorubicin (Giuliani *et al.*, *Proc. Int. Congr. Chemother. 16*:285-70-285-77, 1983), 3'-deamino-3'-hydroxydoxorubicin (Horton *et al.*, *J. Antibiot. 37*(8):853-8, 1984), 4-demethyoxy doxorubicin analogues (Barbieri *et al.*, *Drugs Exp. Clin. Res. 10*(2):85-90, 1984), N-L-leucyl doxorubicin derivatives (Trouet *et al.*, Anthracyclines (*Proc. Int. Symp. Tumor Pharmacother.*), 179-81, 1983), 3'-deamino-3'-(4-methoxy-1-piperidinyl) doxorubicin derivatives (U.S. 4,314,054), 3'-deamino-3'-(4-mortholinyl) doxorubicin derivatives (U.S. 4,301,277), 4'-deoxydoxorubicin and 4'-*o*-methyldoxorubicin (Giuliani *et al.*, *Int. J.* ~~*Mayeer*~~ *Cancer 27*(1):5-13, 1981), aglycone doxorubicin derivatives (Chan & Watson, *J. Pharm. Sci. 67*(12):1748-52, 1978), SM 5887 (*Pharma Japan 1468*:20, 1995), MX-2 (*Pharma Japan 1420*:19, 1994), 4'-deoxy-13(S)-dihydro-4'-iododoxorubicin (EP 275966), morpholinyl doxorubicin derivatives (EPA 434960), 3'-deamino-3'-(4-methoxy-1-piperidinyl) doxorubicin derivatives (U.S. 4,314,054), doxorubicin-14-valerate, morpholinodoxorubicin (U.S. 5,004,606), 3'-deamino-3'-(3"-cyano-4"-morpholinyl doxorubicin; 3'-deamino-3'-(3"-cyano-4"-morpholinyl)-13-dihydoxorubicin; (3'-deamino-3'-(3"-cyano-4"-morpholinyl) daunorubicin; 3'-deamino-3'-(3"-cyano-4"-morpholinyl)-3-dihydrodaunorubicin; and 3'-deamino-3'-(4"-morpholinyl-5-iminodoxorubicin and derivatives (U.S. 4,585,859), 3'-deamino-3'-(4-methoxy-1-piperidinyl) doxorubicin derivatives (U.S. 4,314,054) and 3-deamino-3-(4-morpholinyl) doxorubicin derivatives (U.S. 4,301,277).

Please replace the paragraph beginning at page 19, line 18, with the following redline paragraph:

The taxane paclitaxel is a highly derivatized diterpenoid (Wani *et al.*, *J. Am. Chem. Soc. 93*:2325, 1971) which has been obtained from the harvested and dried bark of *Taxus brevifolia* (Pacific Yew) and *Taxomyces Andreanae* and *Endophytic Fungus* of the Pacific Yew (Stierle *et al.*, *Science 60*:214-216, 1993). It has been formulated into commercial compositions, including the product TAXOL®. Analogs and derivatives of paclitaxel include, for example, commercial products such as TAXOTERE®, as well as compounds such as docetaxel, 10-desacetyl analogues of paclitaxel and 3'N-desbenzoyl-3'N-t-butoxy carbonyl analogues of paclitaxel) (*see generally* Schiff *et al.*, *Nature 277*:665-667, 1979; Long and Fairchild, ~~*Mayeer*~~ *Cancer Research 54*:4355-4361, 1994; Ringel and Horwitz, *J. Nat'l* ~~*Mayeer*~~ *Cancer Inst. 83*(4):288-291, 1991; Pazdur *et al.*, ~~*Mayeer*~~ *Cancer Treat. Rev. 19*(4):351-386, 1993; WO 94/07882; WO 94/07881; WO 94/07880; WO 94/07876; WO 93/23555; WO 93/10076; WO94/00156; WO 93/24476; EP 590267; WO 94/20089; U.S. Patent Nos. 5,294,637; 5,283,253; 5,279,949; 5,274,137; 5,202,448; 5,200,534; 5,229,529; 5,254,580; 5,412,092; 5,395,850; 5,380,751; 5,350,866; 4,857,653; 5,272,171; 5,411,984; 5,248,796; 5,248,796; 5,422,364; 5,300,638; 5,294,637; 5,362,831; 5,440,056; 4,814,470; 5,278,324; 5,352,805; 5,411,984; 5,059,699; 4,942,184; *Tetrahedron Letters 35*(52):9709-9712, 1994; *J. Med. Chem. 35*:4230-4237, 1992; *J. Med. Chem. 34*:992-998, 1991; *J. Natural Prod. 57*(10):1404-1410, 1994; *J. Natural Prod. 57*(11):1580-1583, 1994; *J. Am. Chem. Soc. 110*:6558-6560, 1988). Taxanes may be made utilizing the techniques cited within the references provided herein, or, obtained from a variety of commercial sources, including for example, Sigma Chemical Co., St. Louis, Missouri (T7402 – from *Taxus brevifolia*).

Please replace the paragraph beginning at page 44, line 6, with the following redline paragraph:

In one embodiment, the composition may be packaged in a container. This container may comprise a polymer or a metal foil or a paper product or a combination of these. When the polymers used are polymers that degrade via hydrolysis, the composition may be

packaged in a container that reduces the amount of water absorption by the product compared to the composition that is not packaged in such a container. In another embodiment, the container in which the composition is packaged may contain a ~~desicmayt~~ desiccant. In another embodiment the container packaged composition may be packaged in a secondary container that is more resistant to moisture permeation than the first or primary container of the composition. In another embodiment, a ~~desicmayt~~ desiccant may be placed between the primary and secondary container. Properties of a container that may be important acceptable light transmission characteristics in order to prevent light energy from damaging the composition in the container (refer to USP XXII <661>), an acceptable limit of extractables within the container material (refer to USP XXII), an acceptable barrier capacity for moisture (refer to USP XXII <671>) or oxygen. In the case of oxygen penetration, this may be controlled by including in the container, a positive pressure of an inert gas, such as high purity nitrogen, or a noble gas, such as argon. The term "USP" refers to U.S. Pharmacopeia (*see* www.usp.org, Rockville, MD).

Please replace the paragraph beginning at page 45, line 12, with the following redline paragraph:

In certain embodiments, preferred methods for improving or maintaining a body passageway lumen or cavity includes delivering to an external portion of the body passageway or cavity a delivery device as described herein, for treating or preventing iatrogenic complications of arterial and venous catheterization, complications of vascular dissection, complications of gastrointestinal passageway rupture and dissection, complications associated with vascular surgery, and the like. Exemplary body passageways for use of the instant invention include arteries, veins, the heart, the esophagus, the stomach, the duodenum, the small intestine, the large intestine, biliary tracts, the ureter, the bladder, the urethra, lacrimal ducts, the trachea, bronchi, bronchiole, nasal airways, eustachian tubes, the external auditory ~~mayal~~ canal, vas deferens and fallopian tubes. Exemplary cavities for use of the instant invention include the abdominal cavity, the buccal cavity, the peritoneal cavity, the pericardial cavity, the pelvic cavity, perivisceral cavity, pleural cavity and uterine cavity.

Please replace the paragraph beginning at page 46, line 2, with the following redline paragraph:

Coronary artery bypass graft ("CABG") surgery was introduced in the 1950s, and still remains a highly invasive, open surgical procedure, although less invasive surgical techniques are being developed. CABG surgery is a surgical procedure that is performed to overcome many types of coronary artery blockages. The purpose of bypass surgery is to increase the circulation and nourishment to the heart muscle that has been reduced due to arterial blockage. This procedure involves the surgeon accessing the heart and the diseased arteries, usually through an incision in the middle of the chest. Often, healthy arteries or veins are "harvested" from the patient to create "bypass grafts" that channel the needed blood flow around the blocked portions of the coronary arteries. The arteries or veins are connected from the aorta to the surface of the heart beyond the blockages thereby forming an autologous graft. This allows the blood to flow through these grafts and "bypass" the narrowed or closed vessel. The use of synthetic graft materials to create the "bypass" has been limited due to the lack of the appropriate biocompatibility of these synthetic grafts. CABG has ~~signifimayt~~ significant short term limitations, including medical complications, such as stroke, multiple organ dysfunction, inflammatory response, respiratory failure and post-operative bleeding, each of which may result in death. Another problem associated with CABG is restenosis. Restenosis is typically defined as a renarrowing of an arterial blood vessel within six months of the CABG procedure. It typically occurs in approximately 25% to 45% of patients, and is the result of an excessive healing response to arterial injury after a revascularization procedure. Restenosis may occur within a short period following a procedure or may develop over the course of months or years. Longer term or "-late" restenosis may result from excessive proliferation of scar tissue at the treatment site, the causes of which are not well understood. Thus any product that may reduce the incidence or magnitude of the restenotic process following CABG surgery would greatly enhance the well-being of a patient.

Please replace the paragraph beginning at page 53, line 12, with the following redline paragraph:

In another example, a patient undergoing balloon angioplasty has a sheath inserted into an artery that is to be catheterized (*e.g.*, femoral) and through which the guidewire and balloon angioplasty catheter will be introduced. The sheath remains in place throughout the procedure; oftentimes causing injury to the site of puncture. After the removal of the balloon angioplasty hardware, a needle would be inserted through the skin to the catheterization site and a therapeutic agent (*e.g.*, paclitaxel impregnated into a slow release polymer) or a polymer alone could be infiltrated through the needle or catheter in a circumferential manner directly around the catheterization site. This could be performed around any artery, vein, or graft, but ideal ~~maydidates~~ candidates for this intervention include procedures that require arterial and venous catheterization.

Please replace the paragraph beginning at page 61, line 13, with the following redline paragraph:

The MIT in Section 2 ("toe" section) for Group 1 (controls) was 0.82 ± 0.29 mm (group average ± SD). The low, mid, and high dose paclitaxel groups had values of 0.78 ± 0.30 mm, 0.59 ± 0.14, mm and 0.54 ± 0.23 mm, respectively (5%, 28%, and 34% less than controls), but these differences were not statistically signifimayt at a 95% confidence interval ($p > 0.05$). MIT in section 6 (first full cross section of graft adjacent to the distal anastomosis) in the controls was 1.31 ± 0.82 mm. The low, medium, and high dose paclitaxel groups had MIT in section 6 of 0.38 ± 0.12 mm, 0.31 ± 0.29 mm, and 0.34 ± 0.20 mm, respectively. The reductions in MIT in Groups 1, 2 and 3 were statistically ~~signifimayt~~ significant ($p \leq 0.05$). In sections 7 and 8 (approximately 3 mm and 6 mm past section 6), MIT in the controls was 0.95 ± 0.67 mm and 0.89 ± 0.64 mm, respectively. Although MIT in sections 7 and 8 in all the paclitaxel groups was approximately 70% less than controls, only two values, section 7 Group 3 and section 8 Group 4, were statistically ~~signifimayt~~ significant ($p \leq 0.05$).

Please replace the paragraph beginning at page 61, line 26, with the following redline paragraph:

The IA of the control group was 7.41 ± 5.12 mm, 6.28 ± 4.31 mm, and 5.57 ± 4.62 mm in sections 6, 7, and 8, respectively. In the paclitaxel groups, IA was reduced approximately 70-80%. Reductions in IA for section 6 in Groups 3 and 4 and for section 7 in Group 2, 3 and 4 were statistically ~~signifimayt~~ significant ($p \leq 0.05$).

Please replace the paragraph beginning at page 62, line 1, with the following redline paragraph:

The percent stenosis due to neointima in the control group in section 6 was 28.4 ± 19.5 mm^2. As was the case for the other parameters, stenosis did not decrease markedly at sites 3 and 6 mm into the graft from the anastomosis. Likewise, the effect of paclitaxel on reducing stenosis was similar to the effect on IA, with approximately 70-80% reduction in stenosis, and 7 of 9 values were ~~signifimaytly~~ significantly lower than controls ($p \leq 0.05$).

Please replace the paragraph beginning at page 62, line 11, with the following redline paragraph:

The attrition rate in this study due to early graft occlusion was larger than expected at the outset. The attrition rate appeared to have a dose dependence, which is supported by the histopathology analysis. At the lowest paclitaxel dose, 0.6 mg, there was a marked and ~~signifimayt~~ significant reduction in lesions causing luminal narrowing at the distal end of the graft. This effect did not increase markedly with increased dose, suggesting that the low dose achieved near maximal response in terms of efficacy to inhibit stenosis. The inhibitory effect of paclitaxel does not affect the mechanical integrity of the anastomosis (no evidence of leakage) in the dose range tested. Intraluminal endothelialization is not affected by paclitaxel. Finally, paclitaxel in the doses tested is not toxic to the native artery wall. Thus, the results of this study suggest that low and mid doses represent a useful clinical range of efficacy and safety.

Please replace the paragraph beginning at page 63, line 4, with the following redline paragraph:

Table 3. Percent Change in % Stenosis

Group	Dose	No. Animals[1]	Graft "Toe" Section 2	Graft Section 6	Graft Section 7	Graft Section 8
1	0	5	NA	NA	NA	NA
2	0.6	4	NA	-59%	-66%[2]	-75%[2]
3	1.8	4	NA	-84%[2]	-85%[2]	-75%[2]
4	3.0	3	NA	-81%[2]	-79%[2]	-86%

1 "No. animals" = number patent at study end-point. Animals whose grafts occluded before the study end-point were excluded from analysis.

2 Change statistically ~~signifimayt~~ significant at 95% confidence interval ($p \leq 0.05$).